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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502
Telephone (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 9, 1998

Our Reference No.: 29-53901

Patrick Deasy, President
Dynair Services Inc.
45025 Aviation Drive, Suite 350
Dulles, Virginia 20166

WARNING LETTER

Dear Mr. Deasy:

On March 31, 1998, U.S. Food and Drug Administration (FDA) Investigator Randall P. Zielinski conducted an inspection of your facility at 300 Rodgers Boulevard, Honolulu, Hawaii. The inspection found your operations in serious violation of the federal regulations for interstate conveyance sanitation, Part 1250 (21 CFR 1250), and Section 361 of the Public Health Service Act. The observations, which were listed on Form FDA 483, Inspectional Observations, and discussed with Mr. Jerry Nagatani, Manager, at the conclusion of the inspection are as follows: There was a lack of a backflow prevention device on the water fill line for the water carts; a maintenance wash down garden hose was connected to the potable water service line; the hose on potable water service line was uncapped; and there was no cabinet for storage of the water service hose. A copy of FDA 483 is attached for your information.

The deficiencies found at your facility could result in serious contamination of the potable water supply system. Based on the findings of the inspection, your facility has been assessed to be at a "Provisional" classification. A "Provisional" classification means that if deficiencies are not corrected within thirty (30) working days from receipt of notification, your firm will be placed on "Not Approved" status. A "Not Approved" status means that water would be prohibited from use by interstate conveyances at your facility.

On April 1, 1998, we received a letter from Mr. Nagatani which addresses each of the deficiencies revealed during the inspection. We acknowledge and appreciate the promptness of the response. Mr. Nagatani's letter illustrates that adequate measures were immediately taken to correct the deficiencies found during our inspection. However, it does not include an explanation of preventive measures taken to preclude recurrence of similar violations; therefore,

it does not negate the necessity for the issuance of this letter.

You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to prevent a recurrence of the violations. Your response should be sent to:

Mr. Randall P. Zielinski, CSO/ITS
Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

You may wish to FAX your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]